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| 10/537,533  | 01/30/2006  | Dong Liang           | 514572000500        | 4778             |
| 25225 7590 04/14/2009<br>MORRISON & FOERSTER LLP<br>12531 HIGH BLUFF DRIVE<br>SUITE 100<br>SAN DIEGO, CA 92130-2040 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| BASS, DIRK R  |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 1797  |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/537,533

**Applicant(s)**

LIANG ET AL.

**Examiner**

DIRK BASS

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 29-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-26, 48-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The amendment filed on 11 March 2009 is acknowledged. Claims 1-51 are pending in the application.

In response to the Applicants' traverse of the restriction requirement between groups I-III, the examiner brings to the attention of applicant that independent claim 1 states "said channel layer comprises microfabricated channels on both sides". Giving the broadest reasonable interpretation of "both sides", it can be contemplated that while "both sides" may refer to a top and bottom configuration, it can also refer to a left and right side configuration, thereby fulfilling the limitation as stated in claim 1. Goedert, US 4935040 as relied upon in the restriction requirement filed 15 December 2008, discloses a channel layer comprising microfabricated channels on both the left and right sides of said channel layer, thus teaching the special technical feature shared by groups I-III and establishing a lack of unity among groups I-III.

Therefore, the restriction is made FINAL and claims 29-47 are withdrawn from consideration. Claims 1-28 and 48-51 are considered on merits.

### ***Response to Amendment***

2. In response to the amendment and the Applicants' remarks the examiner withdraws rejection of the claims under 112, second paragraph and modifies the rejection over the prior art.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1, 5, 8, 10-13, 15-24, and 48-49** are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kaltenbach et al., US 5658413 (Kaltenbach).

Regarding claims 1, 5, and 8, Kaltenbach discloses a miniaturized column device (abstract) comprising discrete first (64) and second (66) cover plates (fig. 7A-B) and a discrete channel layer ("substrate 54", fig. 7A-B) all having the same area (fig. 7A-B), wherein said cover plates and channel layers comprise the same compact material (col. 4, l. 3-10, col. 7, l. 25-28, and col. 14, l. 63-67), said channel layer comprises channels on both sides (fig. 7A-B), said channels and sides of said lid layers forming a first (60) and second (62) capillary (fig. 7A-B), said capillaries are connected to each other through a hole to form an integrated capillary ("conduit means 72", fig. 7A-B), said integrated capillary is connected to outside atmosphere on both ends via holes on two outermost cover plates ("apertures 78, 80", fig. 7A-B), said cover plates and channel layer having a thickness ranging from about 0.1 to 5 mm (col. 18, l. 25-34 and col. 19, l. 39-43).

The preamble "A gas chromatograph column" and limitation "suitable for gas chromatography" recited in independent claim 1 are deemed to be statements with regard to intended use and is not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art (See MPEP § 2111.02).

Regarding claims 10-11 and 16-17, Kaltenbach discloses miniaturized columns having microfabricated channels with a width and depth ranging between 3 and 500 microns and similar cross-sectional areas ranging from 5 to about 250,000 square microns (col. 21, l. 34-37).

Claim(s) 12-13 recite limitations regarding a manipulative step to bring about a specific product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (See MPEP 2113).

Regarding claims 15 and 18, Kaltenbach describes a miniaturized column wherein the integrated capillary has semi-circular geometries or serpentine patterns (col. 14, l. 47-59).

Regarding claim 19, Kaltenbach discloses a miniaturized column wherein the wall of the integrated capillary is coated with a thin film of a stationary phase (col. 11, l. 10-24 and col. 22, l. 5-9).

Claim(s) 20-24 recite limitations regarding a manipulative step to bring about a specific product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (See MPEP 2113).

Regarding claims 48-49, Kaltenbach discloses a gas chromatograph column comprising a compact material, wherein said compact material is a polymer (col. 4, l. 3-10 and col. 7, l. 25-28) and lid and channel layers forming said column comprise different compact materials.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. **Claims 2-3, 26-28 and 50-51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaltenbach et al., US 5658413 (Kaltenbach).

Regarding claims 2-3, 26, 28, and 51, while Kaltenbach discloses the claimed invention except for a column comprising at least two lid layers and at least two channel layers, it would have been obvious to one skilled in the art at the time of the invention to produce such a column comprising at least two lid layers and at least two channel layers, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art (See MPEP 2144.04, Section VI, Part B). Furthermore, it can be envisaged from Kaltenbach that a chromatograph column can comprise channel layers wherein one side of a channel layer directly faces another channel of an opposing channel layer to form a capillary (fig. 10).

Regarding claim 50, Kaltenbach discloses the claimed invention except that the chromatography column comprises lid and channel layers, wherein said lid and channel layers have different areas. It would have been an obvious matter of design choice to vary the area of said lid and channel layers, since applicant has not disclosed that varying the areas solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with lid and channel layers being of the same area.

7. **Claims 4 and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaltenbach et al., US 5658413 (Kaltenbach) in view of Craig, US 5792943 (Craig).

Regarding claims 4, 6-7, and 14, Kaltenbach fails to explicitly disclose a chromatography column comprising a compact material wherein said compact material is metal, and the length of said column is at least 4 meters.

Craig discloses a gas chromatography column (col. 12, l. 54 – col. 13, l. 1) comprising a compact material wherein said compact material is metal (see “substrate material”, col. 5, l. 1-8), and the length of said column is at least 4 meters (see “path lengths of up to 15 meters”, col. 17, l. 49-54).

At the time of the invention, it would have been obvious to one skilled in the art to combine the teachings of Craig with the chromatography column of Kaltenbach because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

8. **Claims 6-7, 25, and 50** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaltenbach US 5658413 (Kaltenbach) in view of Goedert, US 4935040 (Goedert).

Kaltenbach fails to explicitly disclose a chromatography column wherein the area of lid and channel layers forming said column is from about 1 to 100cm<sup>2</sup> and further comprises a heater wire on an outside surface of the integrated capillary.

Goedert discloses a gas chromatography column (abstract) wherein the lid layers and channel layers (see "structure 14" and "wafer group 39", fig. 1) have an area ranging from about 1 to about 100 cm<sup>2</sup> (see "5cm x 5cm", col. 4, l. 41-43). Goedert further describes a chromatography column having a heater wire (see "column heater #1", fig. 1 and "hot wire resistive element 166", fig. 9) deposited on an outside surface of the integrated capillary to provide for electric heating of a stationary phase material within the integrated capillary during operation of a gas chromatograph (col. 7, l. 40-52) in order to provide a heating apparatus that is electrically controlled for selective heating of a stationary phase material within the integrated capillary (col. 8, l. 26-28).

At the time of the invention, it would have been obvious to one skilled in the art to combine the teachings of Goedert with the chromatography column of Kaltenbach because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

***Response to Arguments***

9. Applicant's arguments, see page 2, filed 11 March 2009, with respect to the 35 U.S.C. 112 rejection of claim 26 has been fully considered and is persuasive. The rejection of claim 26 has been withdrawn.

Applicant's arguments with respect to the 35 U.S.C. 102 and 103 rejections of claims 1-28 have been considered but are moot in view of the new ground(s) of rejection.

Kaltenbach is relied upon for the 35 U.S.C. 102(b) rejection of independent claim 1. Kaltenbach clearly teaches discrete layers of a chromatography column as seen in fig. 1B and fig. 7A-B, thereby overcoming the amendment and anticipating independent claim 1. Kaltenbach is also relied upon for the 35 U.S.C. 103(a) obviousness rejections of independent claims 26 and 51. Kaltenbach teaches discrete lid and channel layers and also makes obvious a plurality of lid and channel layers to form a chromatography column as seen in fig. 1B and fig. 7A-B.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

4/13/2009

/Yelena G. Gakh/  
Primary Examiner, Art Unit 1797

/DRB/

Dirk R. Bass